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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,344	01/04/2002	Daniel M. Cimbora	2318-288-ll	2255

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,344	CIMBORA ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,46 and 48-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,46 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RC

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 1/28/05 has been entered into the record.

B. Claims 1, 46 and 48-50 are pending and are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 101

A. The rejection of claims 1, 46 and 48-50 under 35 USC 101 has been withdraw in view of Applicants' arguments that AKT1 and AKT2 are involved in cell proliferation and apoptosis and that the claimed complexes can be used as therapeutic targets for such events.

3. Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1, 46 and 48-50 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action mailed 12/6/04. While Applicants have asserted that AKT1 and AKT2 are involved in cell proliferation and apoptosis and that the claimed complexes can be used as therapeutic targets for such events. The claims recite both protein complexes as well as methods of using these complexes to screen for compounds which can modulate these interactions. However, Applicants have not taught how to use the present invention.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive. Applicants have added the limitation into claim 1 which include "**a homologue at least 90% identical**" to AKT1, AKT2, FNTA, TRPD, KIAA0728, PPL, Golgin-84, CL1C1, ARK7A2 and TPRD (not TRPD). Proteins which are "at least 90% identical" to the proteins of claim 1 would have one or more amino acid substitutions, deletions, insertions and/or additions to the full-length proteins. Applicants provide no guidance or working examples of proteins which are at least 90% identical to the full-length protein of the claims, nor do they provide a *function* of these proteins. Applicants have provided no guidance as to what critical residues are required to maintain the functional characteristics of AKT1, AKT2, FNTA, TRPD, KIAA0728, PPL, Golgin-84, CL1C1, ARK7A2 and TPRD. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional protein which is less than 100% identical to that of AKT1, AKT2, FNTA, TRPD, KIAA0728, PPL, Golgin-84, CL1C1, ARK7A2 and TPRD.

Furthermore, page 8 of the specification states that:

> Aktl and Akt2 are serine/threonine protein kinases capable of phosphorylating a variety of known proteins. Akt1 and Akt2 are activated by platelet-derived growth factor (PDGF), a growth factor involved in the decision between cellular proliferation and apoptosis. AKT kinases are also activated by insulin-like growth factor (1GF1), and in this capacity are involved in survival of cerebellar neurons). Furthermore, Aktl is involved in the activation of NFkB by tumor necrosis factor (TNF). Akt2 has been shown to be associated with pancreatic carcinomas. Akt kinases have been implicated in insulin-regulated glucose transport and the development of non-insulin dependent diabetes mellitus.

Applicants also provide Tables 1-10 in the specification, as well as numerous other paragraphs which discuss kinases (e.g. [0020] – [0030]), their interactions with other proteins as well as discussion of the vast array of potential roles of these kinases and various other proteins of the claimed complexes and methods. While Applicants have disclosed that the proteins of the invention are associated with numerous pathways and roles in a cell, they have not taught how the artisan is to use the complexes other than for the general purpose of screening for ligands which interfere with their formation. Applicants have not taught whether increases, or decreases, in specific complex formations would be beneficial, nor, regardless, what the results would allow the artisan to do with the knowledge. Much of Applicants disclosure uses phrases such as "**involved in,**" "**associated with,**" "**likely plays a role in,**" as well as general functions such as "phosphorylating a variety of known proteins." This information does not provide sufficient guidance to teach the artisan how to use the present invention, especially in light of the fact that the claimed proteins do not have to be 100% identical to known proteins. However, reciting a function of these homologues would, itself, not remedy the situation.

Given the lack of guidance of what the specific functions are of the claimed complexes, as well as what useable information can be gathered from screening complexes to identify modulators of these interactions, it is unpredictable to the artisan how to use the information gathered from these screening methods. Claim limitations such as "promoting the interaction" and "inhibiting the interaction of said proteins" does not provide sufficient insight into how to use the claimed methods insofar as what useful conclusions can be gathered.

In summary, the breadth of the claims is excessive with regard to Applicants claiming "a homologue at least 90% identical" to AKT1, AKT2, FNTA, TRPD, KIAA0728, PPL, Golgin-84, CL1C1, ARK7A2 and TPRD. Applicants provide no guidance or working examples of proteins which are at least 90% identical to the full-length proteins of the claims, nor do they provide a *function* of these proteins. Furthermore, there is a lack of guidance of what the specific functions are of the claimed complexes, as well as what useable information can be gathered from screening complexes to identify modulators of these interactions. For these reasons, it is unpredictable to the artisan how to make functional complexes, or how to use the claimed screening methods, or the compounds identified by these methods. For these reasons, the Examiner holds that undue experimentation is required to practice the claimed invention.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1, 46 and 48-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The claims recite "**a homologue at least 90% identical**" to AKT1, AKT2, FNTA, TRPD, KIAA0728, PPL, Golgin-84, CL1C1, ARK7A2 and TPRD (not TRPD). Proteins which are "at least 90% identical" to the proteins of claim 1 would have one or more amino acid substitutions, deletions, insertions and/or additions to the full-length proteins.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of

the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "AKT1, AKT2, FNTA, TRPD, KIAA0728, PPL, Golgin-84, CL1C1, ARK7A2 and TPRD" alone are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Conclusion

A. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER
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